UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,290	09/24/2003	Daikichi Fukushima	Q77043	3831

23373 7590 02/08/2006

SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER	
WHITE, EVERETT NMN	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/668,290	FUKUSHIMA ET AL.	
	Examiner	Art Unit	
	Everett White	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 9 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/24/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The determination that "undue experimentation" would have been needed to use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404.

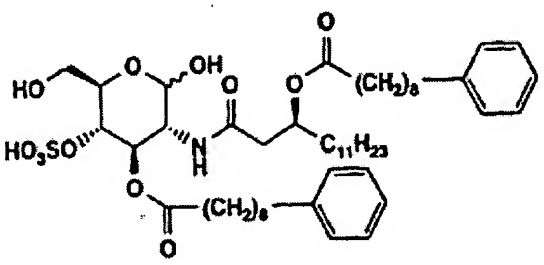
There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims

The breadth of the instant claims is seen to encompass methods for the prevention and/or treatment of HIV infectious diseases, which comprises administering to a subject in need thereof an effective amount of 2-deoxy-2-[3S-(9-phenylnonanoyl-

oxy)tetradecanoyl]amino-3-O-(9-phenylnonanoyl)-4-O-sulfo-D-glucopyranose represented by formula (I-a):



(I-a)

or a non-toxic salt thereof. This encompasses administration of the active agent to healthy patients who subsequently do not obtain HIV infectious diseases due to the preventive measures and administering to patients who have an HIV infectious disease and benefit from the claimed treatment.

The nature of the invention

Currently, there are no known agents that prevent HIV infectious diseases. The art does not disclose an active agent or combination of active agents, which is recognized as prevention for the conditions cited supra. The prior art does not teach or disclose a treatment modality wherein healthy subjects are treated with an active agent or agent(s) and there is evidence that none of the associated symptoms or disease state characteristics are ever manifested. The disclosure does not direct the skilled artisan to any art that satisfies the requirement for preventing a disease state associated with HIV infections.

The state of the prior art

The instant specification teaches that acquired immune deficiency syndrome (AIDS) caused by the infection of human immunodeficiency virus (HIV) is one of the diseases whose methods for treatment are recenty most desired earnestly. The instant specification discloses that when the infection of HIV to CD4 positive cells is established, HIV repeats multiplication in a patient's body, and then fatally destroys T cell, which takes charge of the immunological function. The specification teaches that during the process, immunological function is gradually deteriorated to result in the

appearance of various immunologically deficient states such as pyrexia, diarrhea and swelling of lymph nodes, which, in the course of time, tend to be complicated by various opportunistic infections such as Kalini pneumonia. Such a situation, as taught in the instant specification, is regarded as occurrence of AIDS. The specification discloses that a variety of methods for prevention and treatment have been attempted against AIDS (for example, (1) inhibition of the multiplication of HIV by administering a reverse transcriptase inhibitor or a protease inhibitor, (2) prevention or alleviation of opportunistic infections by administering a medicament having immunopotentiating activity).

The level of one of ordinary skill

The level of skill is that of a MD or PhD.

The level of predictability in the art

Since the art does not disclose any agents that are effective in preventing HIV infectious diseases, the skilled artisan would not predict, in the absence of proof to the contrary, that the active agent instantly used in the claimed method is efficacious in preventing said diseases as broadly claimed. The assertion of a broad application as set forth in the instant method claim necessarily requires evidence to support applicant's asserted method. The examiner notes there are no known agents recognized as preventive agents of HIV infectious diseases, and one of skill in this art could not predict, from the evidence of record, that the active agent asserted to be useful in the instantly claimed method, can indeed prevent HIV infectious diseases.

The amount of direction provided by the inventor

The examiner notes, there is not seen sufficient guidance provided in the form of administration profiles of the active agent to a subject or reference to same in the prior art to provide the skilled artisan with sufficient guidance to practice the instant preventive method. Prevention is seen to encompass administering the active agent to a subject, exposing the subject to HIV viruses, and noting that the HIV infectious diseases never manifest themselves. The data and evidence provided in the instant disclosure leads the examiner to doubt the objective truth of assertions of prevention of HIV infectious diseases.

The existence of working examples

A conclusion of lack of enablement means that, based on the evidence regarding the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993). The *in vitro* experimental procedures disclosed on page 74 in the instant specification were noted, wherein human peripheral blood monocyte was stimulated with fetal bovine serum and infected with viruses of HIV in the presence of test compounds. However, success with *in vitro* experiments does not equal successful treatment or prevention of HIV infectious diseases in a human subject. Also, it is not clear in the experiment that the compound set forth in the method of instant Claim 9 is one of the test compounds set forth in the experiments. There is not seen in the disclosure, sufficient evidence to support Applicant's claims of prevention. There is not seen sufficient working examples or data from references of the prior art providing a nexus between that which applicant asserts as proof of a method for preventing HIV infectious diseases and evidence currently provided on the record to support methods drawn to preventing any condition.

The quantity of experimentation needed to make or use the invention

More information is needed which clearly shows that the artisan has effectively prevented and/or treated successfully HIV infectious diseases by administering to a subject the instantly claimed active agent or some correlation to specifically establish the usefulness of the instantly claimed prevention and/or treatment.

Summary

3. Claim 9, the only pending claim, is rejected.

Examiner's Telephone Number, Fax Number, and Other Information

4. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit out website at **www.uspto.gov** and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang, can be reach on (571) 272-0627. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

E. White

E. White

9/2/06

Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600